

minor infections, since certain cases of serious blood dyscrasias (aplastic anemia, thrombocytopenic purpura, granulocytopenia, and pancytopenia) have been associated with the administration of chloramphenicol, and the statement that when prolonged or intermittent administration is required, adequate blood studies should be carried out; 502(1)—the article was a drug, chloramphenicol, and was not from a batch with respect to which a certificate or release had been issued pursuant to 507, and it was not exempt from such requirements by regulations promulgated pursuant to 507; and 503(b) (4)—the article was a drug subject to the provisions of 503(b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 11-14-60. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

6367. Amphetamine sulfate tablets, dextro-amphetamine tablets, and Dexobarbital tablets. (F.D.C. No. 43630. S. Nos. 74-662/7 P, 74-669/70 P.)

QUANTITY: 24 1,000-tablet unlabeled btls. of amphetamine sulfate, 15 1,000-tablet labeled btls. of dextro-amphetamine sulfate tablets, and 3 1,000-tablet btls. of Dexobarbital, in possession of Robert Rubin Yablon, t/a Sharon Rexall Drugs, Chicago, Ill.

SHIPPED: Prior to 10-28-59, from outside the State of Illinois.

LIBELED: 10-30-59, N. Dist. Ill.; amended 9-23-60.

CHARGE: 502(b) (1)—while held for sale, the articles (all lots) failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; 502(b) (2)—the article (24 btls.) failed to bear an accurate statement of the quantity of contents in terms of weight, measure, or numerical count; 502(f) (1)—the labeling of the articles (all lots) failed to bear adequate directions for use and the articles were not exempt from such requirement since they were not to be dispensed upon prescription in accordance with Section 503(b) (1); and 502(i) (2)—the article (15 btls.) was an imitation of another drug, namely, Dexedrine Sulfate.

DISPOSITION: 11-7-60. Robert Yablon, claimant, having filed an answer denying that the articles were misbranded, and the Government having filed a motion for summary judgment on the ground that there was no genuine issue of material fact between the parties in regard to the misbranding of the articles under 502(b) (1) and (2), and the claimant having failed to make any objection to such motion, judgment of condemnation was entered and the articles were ordered destroyed.

6368. Lone Indian Herb Tonic. (F.D.C. No. 44432. S. No. 71-277 P.)

QUANTITY: Undetermined number of 8-oz. btls. at Baxter, Ky., in possession of B. Daniel Fannon, t/a Jot-Em-Down Store.

SHIPPED: The powdered aloes ingredient of the article had been shipped from Knoxville, Tenn., on an unknown date.

LABEL IN PART: "NBS Lone Indian Herb Tonic Nerve, Blood & Stomach
* * * This is a mild laxative Made from the Apple Family: Bitter Apple, Orange Apple, Aloes Powders, Salicylic, Red Cherry Powders and Distilled

*See also No. 6366.

water—Contains Vitamins of the Fruit Family. Directions * * * Lone Indian Remedies, Baxter, Ky.”

ACCOMPANYING LABELING: Window streamers reading in part “Lone Indian Herb Tonic Nerve—Blood and Stomach—Well known for Rheumatism and Arthritis Pain,” and a number of loose bottle labels.

LIBELED: 4-15-60, E. Dist. Ky.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that it was an adequate and effective treatment for constipation, liver, kidney, and bladder troubles; swelling of joints and muscles, with aches and pains of the body; a dizzy feeling of the head; no appetite; and no rest at night; 502(b) (2)—the article failed to bear a label containing an accurate statement of the quantity of contents; and 502(f) (2)—the label of the article failed to bear a warning that its use should be discontinued when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present; and that frequent or prolonged use of the article may result in dependence on laxatives.

DISPOSITION: 10-12-60. Default—destruction.

DRUG ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

6369. Lobelia herb. (F.D.C. No. 44612. S. Nos. 35-326/7 R.)

QUANTITY: 3 bales at New York, N.Y.

SHIPPED: 10-20-58, from Bristol, Tenn.

LIBELED: 6-22-60, S. Dist. N.Y.

CHARGE: 501(a) (1)—while held for sale, the article contained insects.

DISPOSITION: 9-12-60. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

6370. Folabin. (F.D.C. No. 44816. S. No. 26-563 R.)

QUANTITY: 107 cartoned vials at Los Angeles, Calif.

SHIPPED: 7-1-60, from Cedar Rapids, Iowa, by Paul Maney Laboratories, Inc., Div. of Michigan Chemical Corp.

LABEL IN PART: (Vial) “10 cc. X-558 Folabin Double Strength * * * Paul Maney Laboratories, Cedar Rapids, Iowa * * * 5863.”

RESULTS OF INVESTIGATION: Examination showed that the article contained about 75 percent of the labeled amount of vitamin B₁₂.

LIBELED: 10-11-60, S. Dist. Calif.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it purported to possess; and 502(a)—the label statements “Each cc. Contains: Vitamin B₁₂ Activity * * * Equivalent to Cyanocobalamin * * * 10 mcgm. * * * Vit. B₁₂ Cryst. 50 mcgm. Total B₁₂ Activity 60 mcgm.” were false and misleading.

DISPOSITION: 11-2-60. Default—destruction.

6371. Contact lens wetting solution. (F.D.C. No. 44580. S. Nos. 34-771 R, 34-773 R.)

QUANTITY: 752 5-cc. vials and 72 cartoned pt. btls. at New York, N.Y.

SHIPPED: 1-11-60 and 1-26-60, from Wauconda, Ill., by Micon Laboratories.